



WITH SUPPORT FROM



Workplace Commons

Testing Commons

Evidence Commons

T3 Blog

Meet Our Team

Webinars

Media

Get Involved

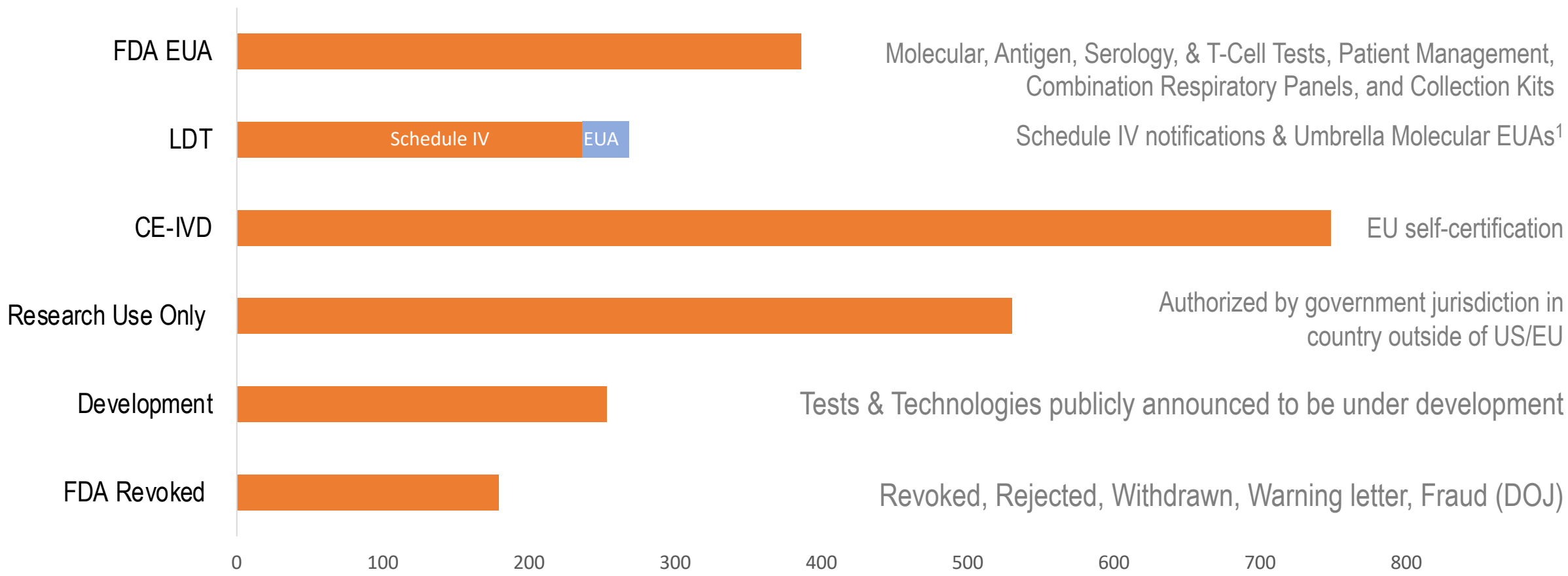
TestingCommons.com

A one-stop reliable source for comprehensive information about COVID-19 tests worldwide. Search all tests in the market and in the pipeline by multiple parameters including test type, technology, regulatory status, country of origin and more.

TestingCommons.com, part of COVID Diagnostics Commons initiative
at Arizona State University's College of Health Solutions

Testing Commons is made possible with support from The Rockefeller Foundation

TestingCommons.com Pandemic Review



1. n/a after 10/7/20 when HHS/FDA announced policy to not require authorization for any LDT
2. 19% of tests with approval internationally have been granted EUA by the US FDA

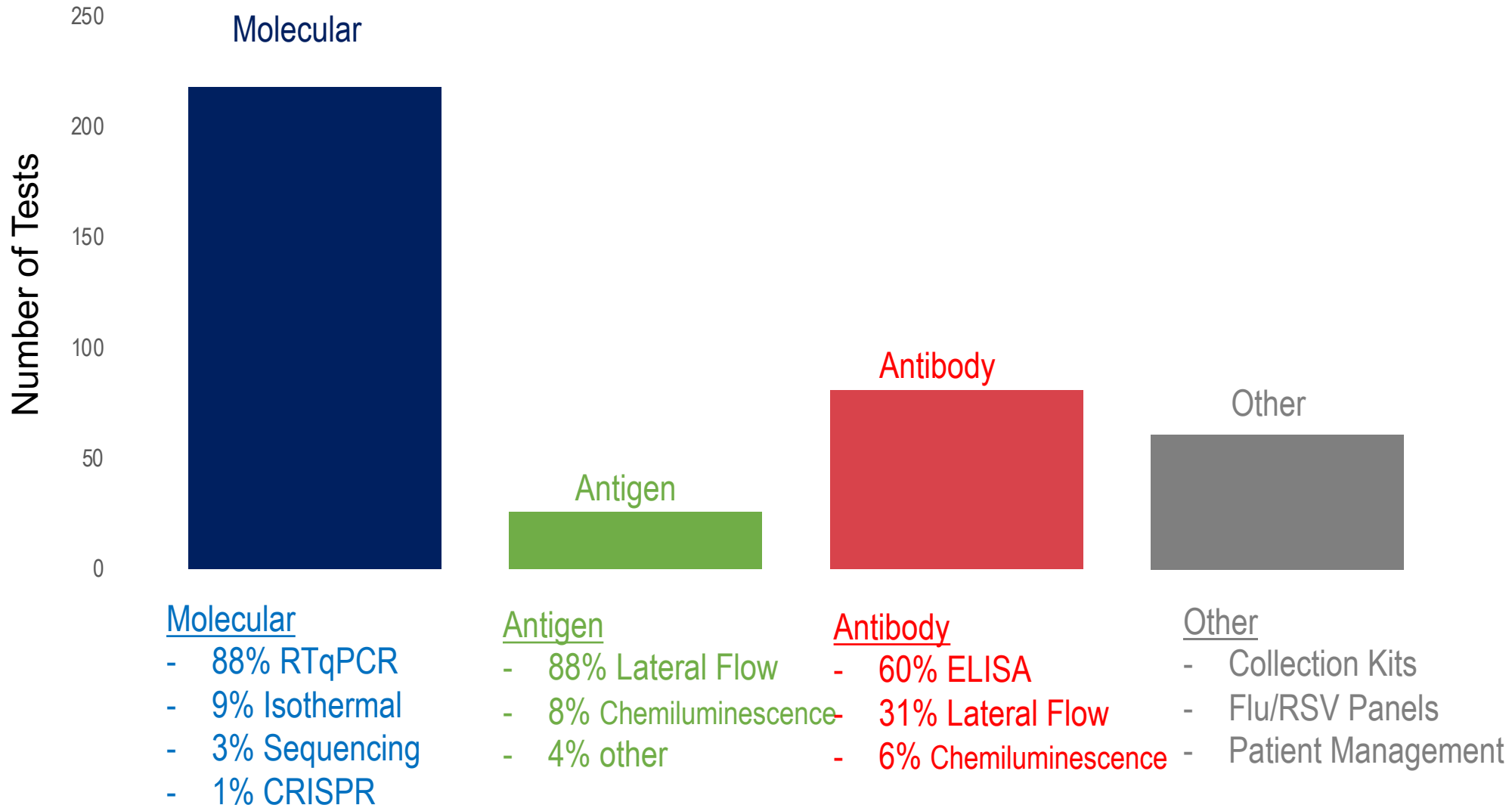
Pandemic Total through 6/30/21

US FDA EUA Test Classifications



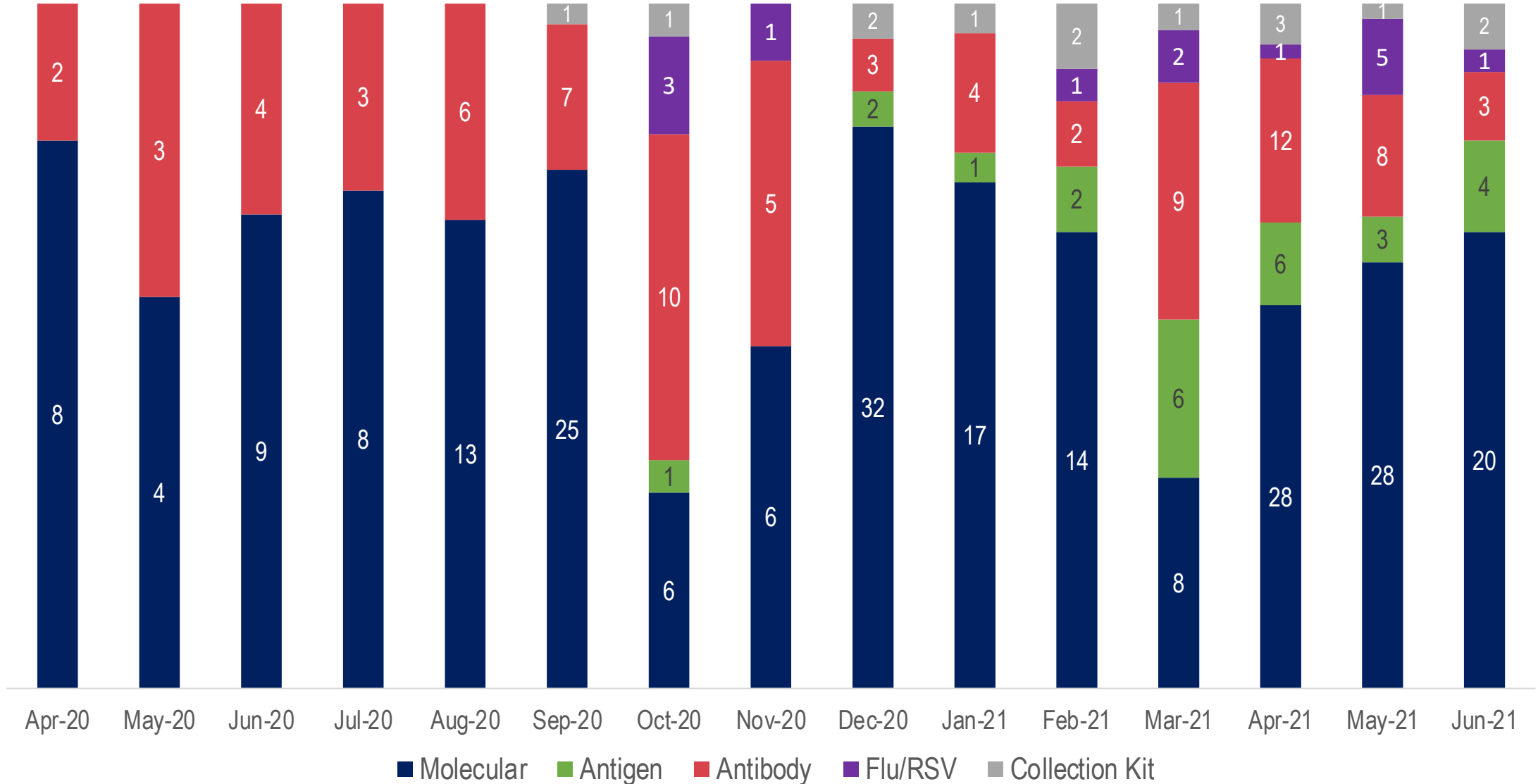
- Tests:
 - Molecular Tests (including Appendix A LDTs and Flu panels)
 - Antigen Tests (including Flu panels)
 - Patient Management Tests (IL6)
 - Serology (Antibody) Tests (including cellular immunity)
- Collection Kits
 - Home Collection Kits (Nasal Swabs or Saliva)
- Test Attributes:
 - Test Location (Lab vs. POC vs. Home)
 - Screening (Asymptomatic)
 - Serial Screening
 - Pooling
 - OTC vs Prescription

US FDA Emergency Use Authorizations



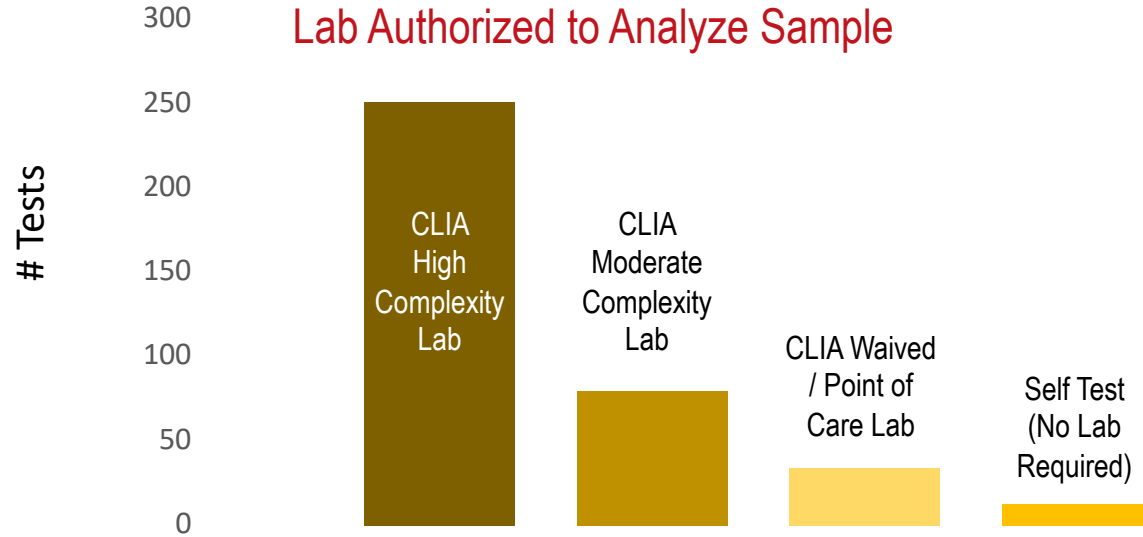
Pandemic Total through 6/30/21

Timeline of EUA Issuances and Amendments by Type

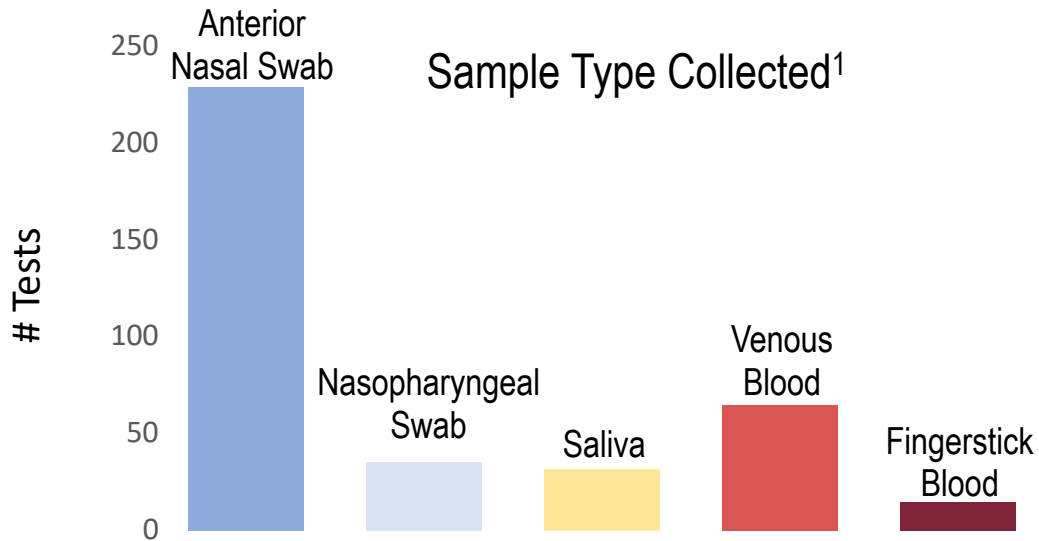


Profile of US FDA EUA's

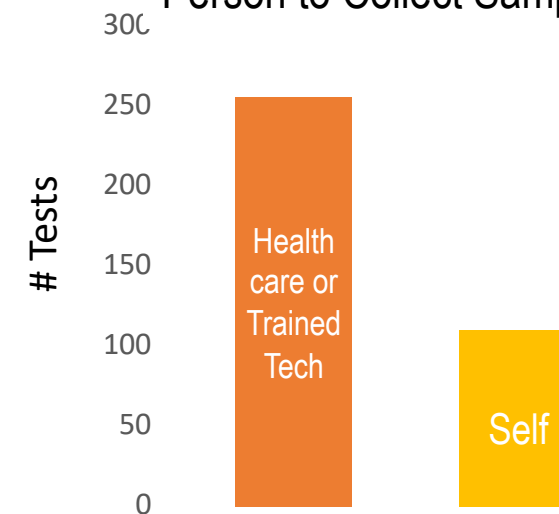
Lab Authorized to Analyze Sample



Sample Type Collected¹



Person to Collect Sample²



1. Only a single Swab type per test counted here, in least to most invasive priority order: Saliva; ANS; lastly NPS/OPS. All PCR tests are sensitive enough to work with nearly all of these swab types: later authorizations specify ANS in addition to other swab methods. 2. No specific Healthcare Professional training is required by the EUA (at Laboratory discretion)

11 EUA's for Comprehensive At-Home Tests



MOLECULAR TESTS (3)

ANTIGEN TESTS (8)

RX TESTS (4)

- Lucira COVID-19 All-In-One Test Kit

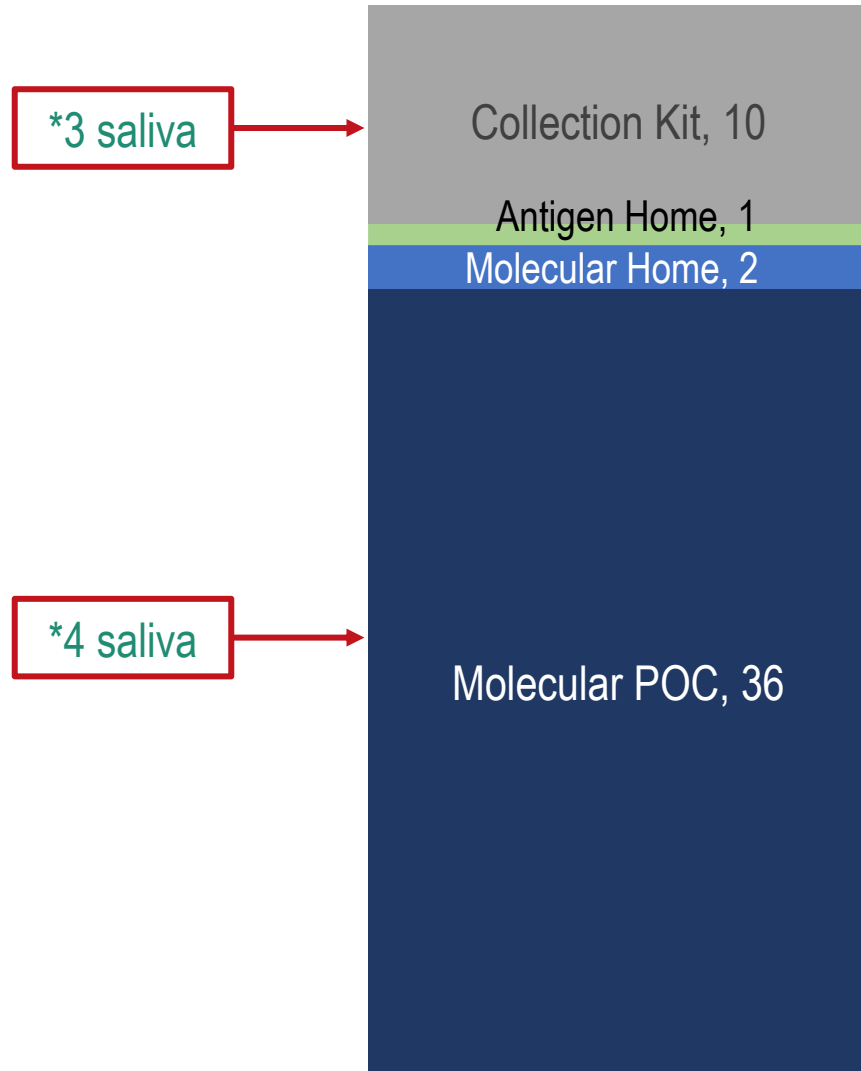
- Abbott BinaxNOW COVID-19 Ag Card Home Test
- OraSure InteliSwab COVID-19 Rapid Test Rx
- Quidel QuickVue At-Home OTC COVID-19 Test

OTC TESTS (7)

- Cue COVID-19 Test for Home and Over The Counter (OTC) Use
- Lucira CHECK-IT COVID-19 Test Kit

- Abbott BinaxNOW COVID-19 Ag Card 2 Home Test
- Abbott BinaxNOW COVID-19 Antigen Self Test
- Ellume COVID-19 Home Test
- OraSure InteliSwab COVID-19 Rapid Test
- Quidel QuickVue At-Home OTC COVID-19 Test

EUA's for Asymptomatic Screening & Serial Screening



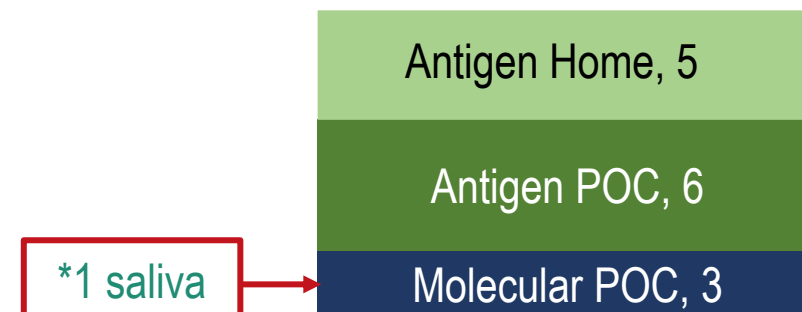
Screening (49)



A. PROPOSED INTENDED USE

FDA recommends including the following in the requested intended use:

[...individuals without symptoms or other epidemiological reasons to suspect COVID-19 infection, when tested twice over two (or three) days with at least 24 hours (and no more than 36 hours) between tests.]



Serial Screening (14)

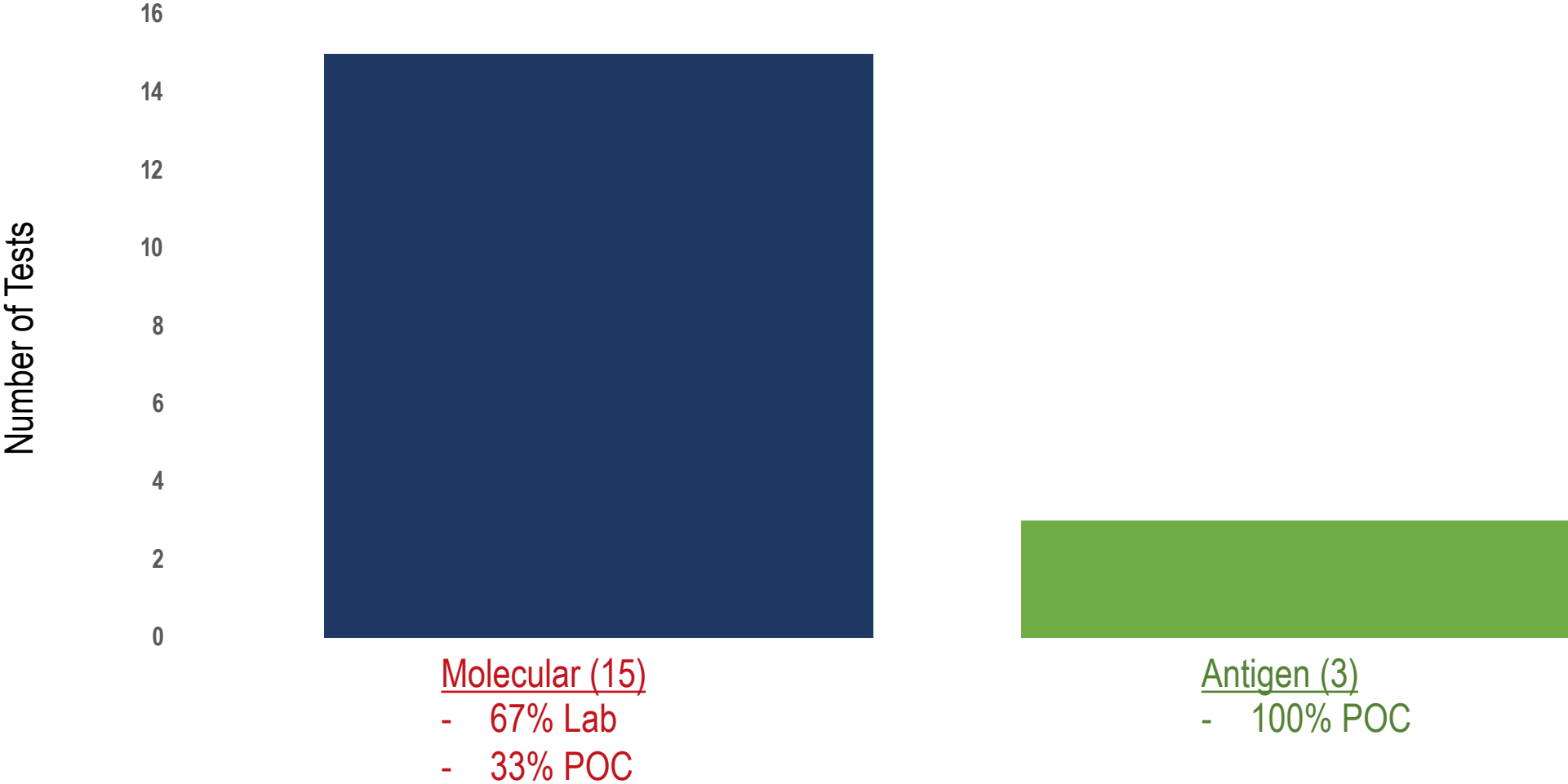
28 Antigen Tests with EUAs

Instrument read

	CLIA High/Moderate (Laboratory)	CLIA Waived (Physician Office)	Home
Instrument read	Celltrion Sampinute DiaSorin LIAISON Ortho VITROS Qorvo Omnia Quanterix Simoa	BD Veritor BD Veritor + Flu A/B Luminostics Clip LumiraDx Quidel Sofia FIA Quidel Sofia2+Flu	Ellume OTC
Visual read		Access Bio CareStart BinaxNOW Card BinaxNOW 2 Card Celltrion DiaTrust InBios SCoV-2 OraSure Inteliswab Pro Princeton Status+Flu Salofa Sienna-Clarity Quidel QuickVue	BinaxNOW Home Rx BinaxNOW Self OTC BinaxNOW Telehealth OraSure Inteliswab RX OraSure Inteliswab OTC Quidel QuickVue Rx Quidel QuickVue OTC

Pandemic Total
through 6/30/21

18 EUA's for Respiratory Panels (Flu, RSV, etc.)



Pandemic Total through 6/30/21

18 EUA's for Respiratory Panels (Flu, RSV, etc.)



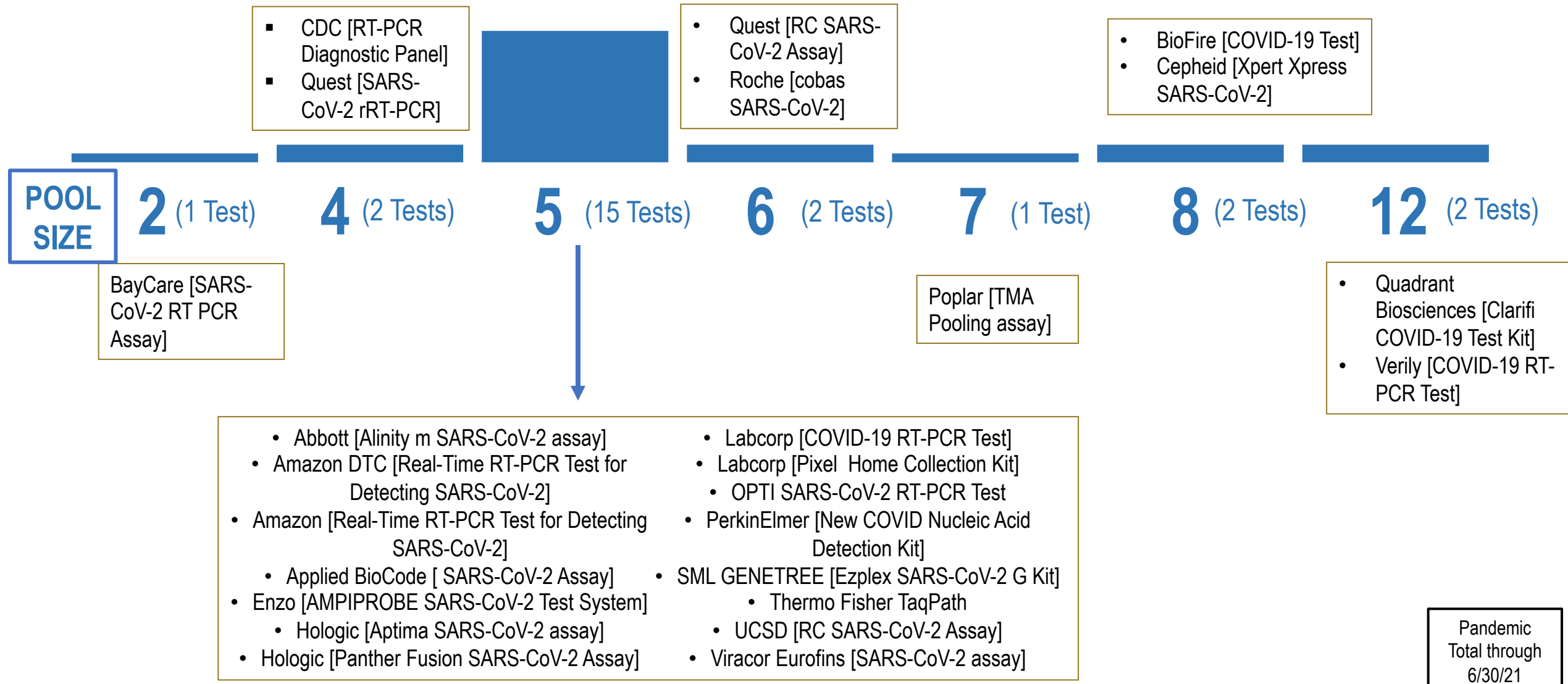
Molecular Respiratory Combination Tests (15)

- Abbott Alinity m Resp-4-Plex
- BD for BD MAX system
- BioFire Diagnostics Respiratory Panel 2.1 EZ
- Bio-Rad Reliance
- CDC Flu C2 Multiplex Assay
- Cepheid Xpert Xpress
- GenMark ePlex Respiratory Pathogen Panel 2
- Hologic Aptima
- Luminex NxTAG Respiratory Pathogen Panel + SARS-CoV-2
- NeuMoDx Flu A-B/RSV/SARS-CoV-2 Vantage Assay
- QIAGEN GmbH QIAstat-Dx Respiratory SARS-CoV-2 Panel
- Quest RC COVID-19+Flu RT-PCR
- Roche cobas
- Roche cobas for use with Liat system
- Thermo Fisher TaqPath

Antigen Respiratory Combination Tests (3)

- BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu A+B
- Princeton BioMeditech Corp. Status COVID-19/Flu
- Quidel Sofia 2 Flu + SARS Antigen FIA

28 EUA's for Testing of Pooled Samples

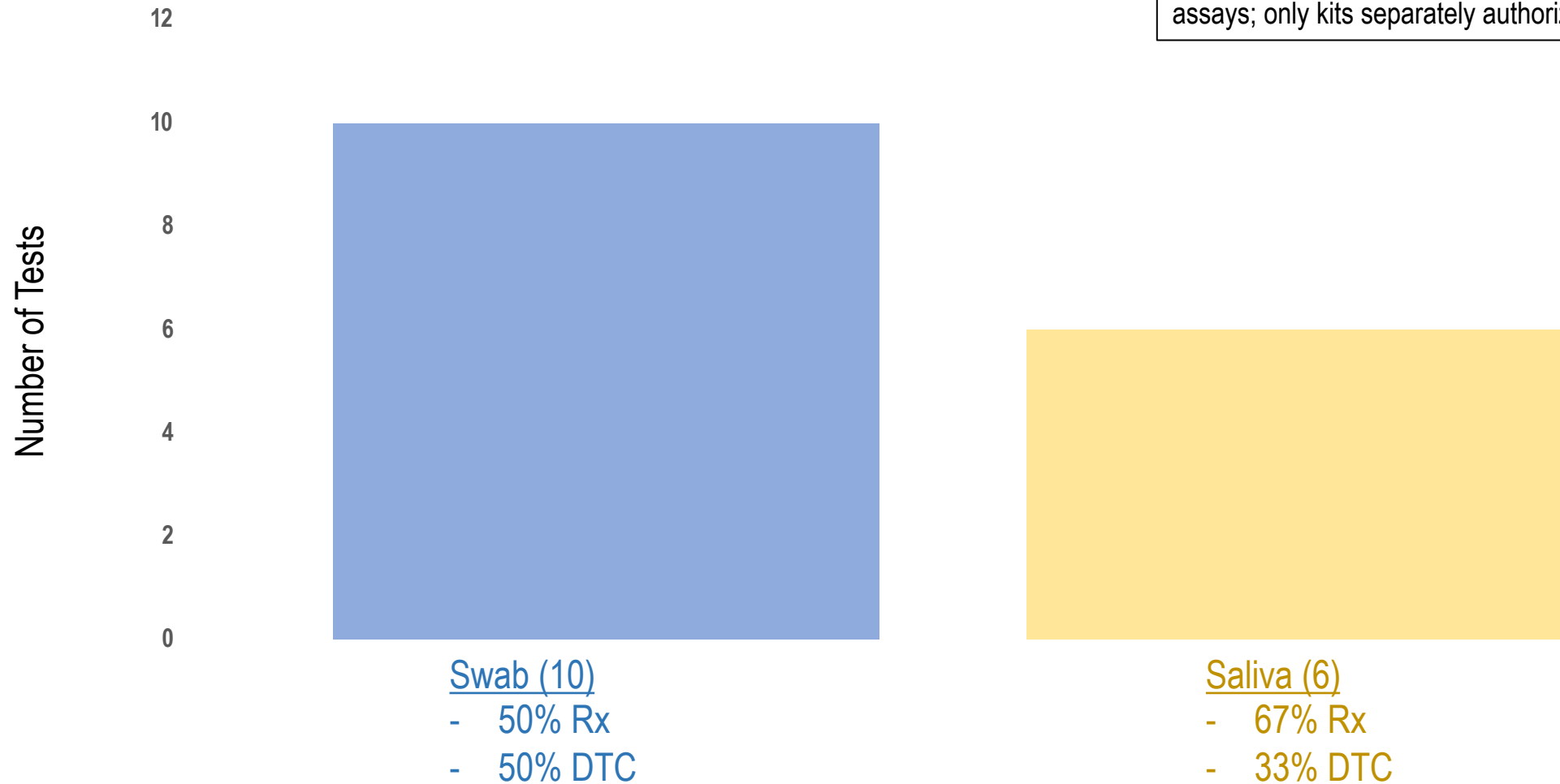


Pandemic Total through 6/30/21

16 EUA's for Independent Home Specimen Collection Kits



Note: Does not include collection kits included with proprietary assays; only kits separately authorized with independent EUA's



Pandemic Total through 6/30/21



Swab Collection Kits (10)

- binx health At-Home Nasal Swab COVID-19 Sample Collection Kit
- Clinical Enterprises EmpowerDX COVID-19 Home Collection Kit DTC
- Color COVID-19 Self-Swab Collection Kit
- Color COVID-19 Self-Swab Collection Kit DTC
- Color COVID-19 Self-Swab Collection Kit with Saline
- Everlywell COVID-19 Test Home Collection Kit
- Everlywell COVID-19 Test Home Collection Kit DTC
- GetMyDNA COVID-19 Test Home Collection Kit
- Kroger Health COVID-19 Test Home Collection Kit
- RapidRona Self-Collection Kit

Note: Does not include collection kits included with proprietary assays; only kits separately authorized with independent EUA's

Saliva Collection Kits (6)

- DNA GenoTech OMNIgene·ORAL OM-505 and OME-505 (OMNIgene·ORAL) Saliva Collection Device
- DNA GenoTech ORAcollect·RNA OR-100 and ORAcollect·RNA ORE-100 Saliva Collection Device
- Phosphorus Diagnostics LLC Pinpoint by Phosphorus COVID-19 Test Home Collection Kit DTC
- Spectrum Solutions SDNA-1000 Saliva Collection Device
- WREN Laboratories COVID-19 Saliva Test Collection Kit DTC
- Yale School of Public Health SalivaDirect

CE-IVD Certified Tests (Mostly Europe)



Workplace Commons

Testing Commons

Evidence Commons

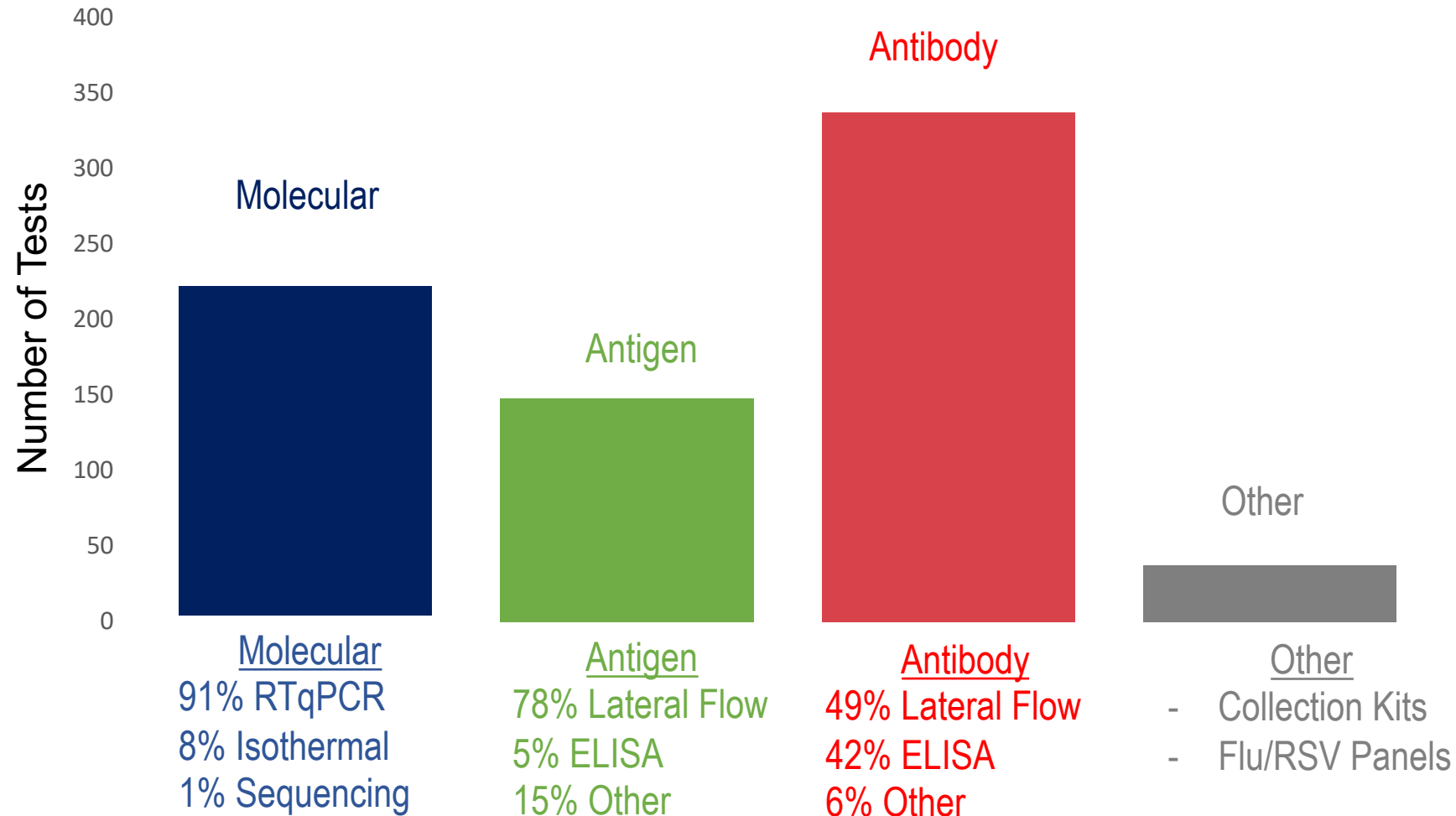
T3 Blog

Meet Our Team

Webinars

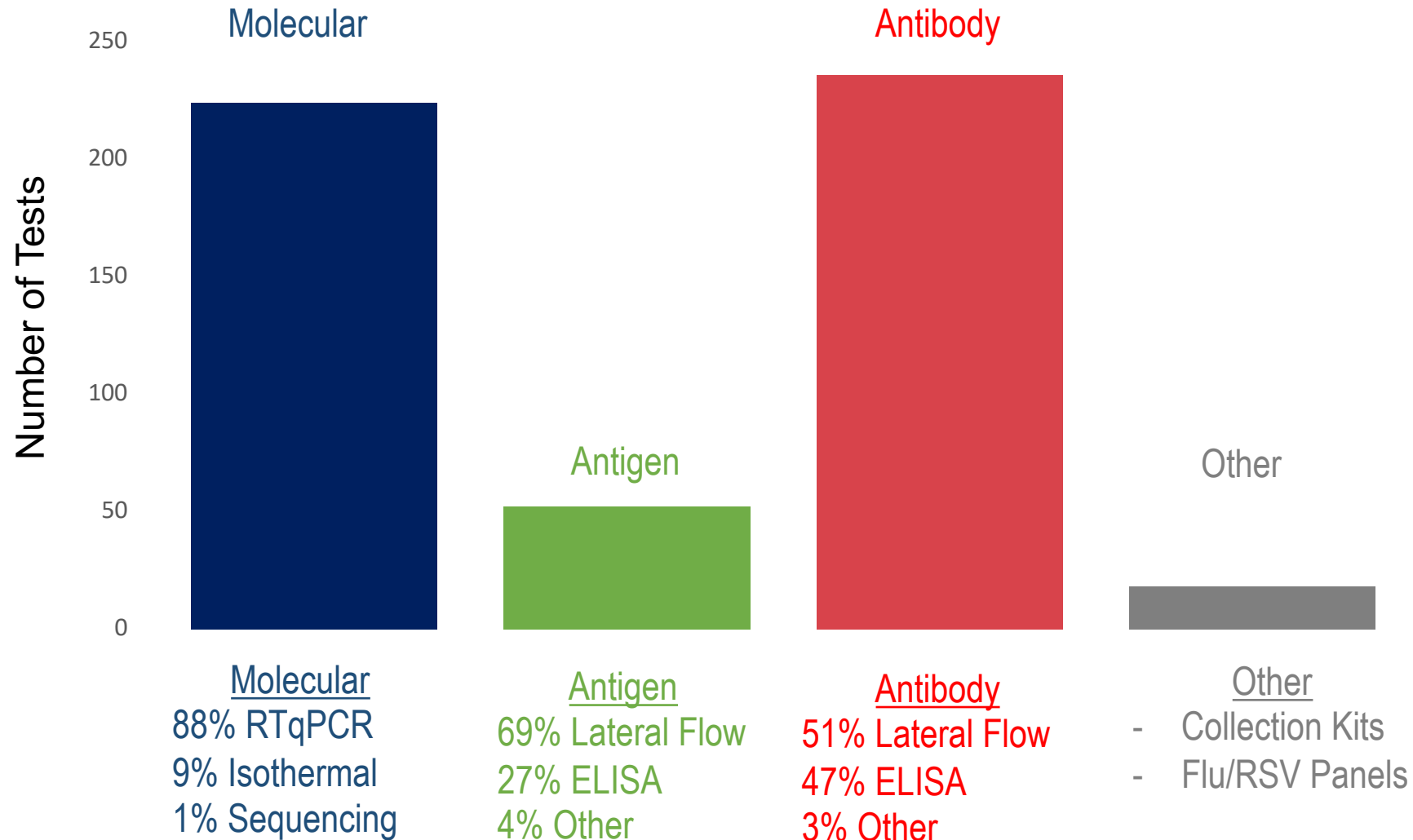
Media

Get Involved



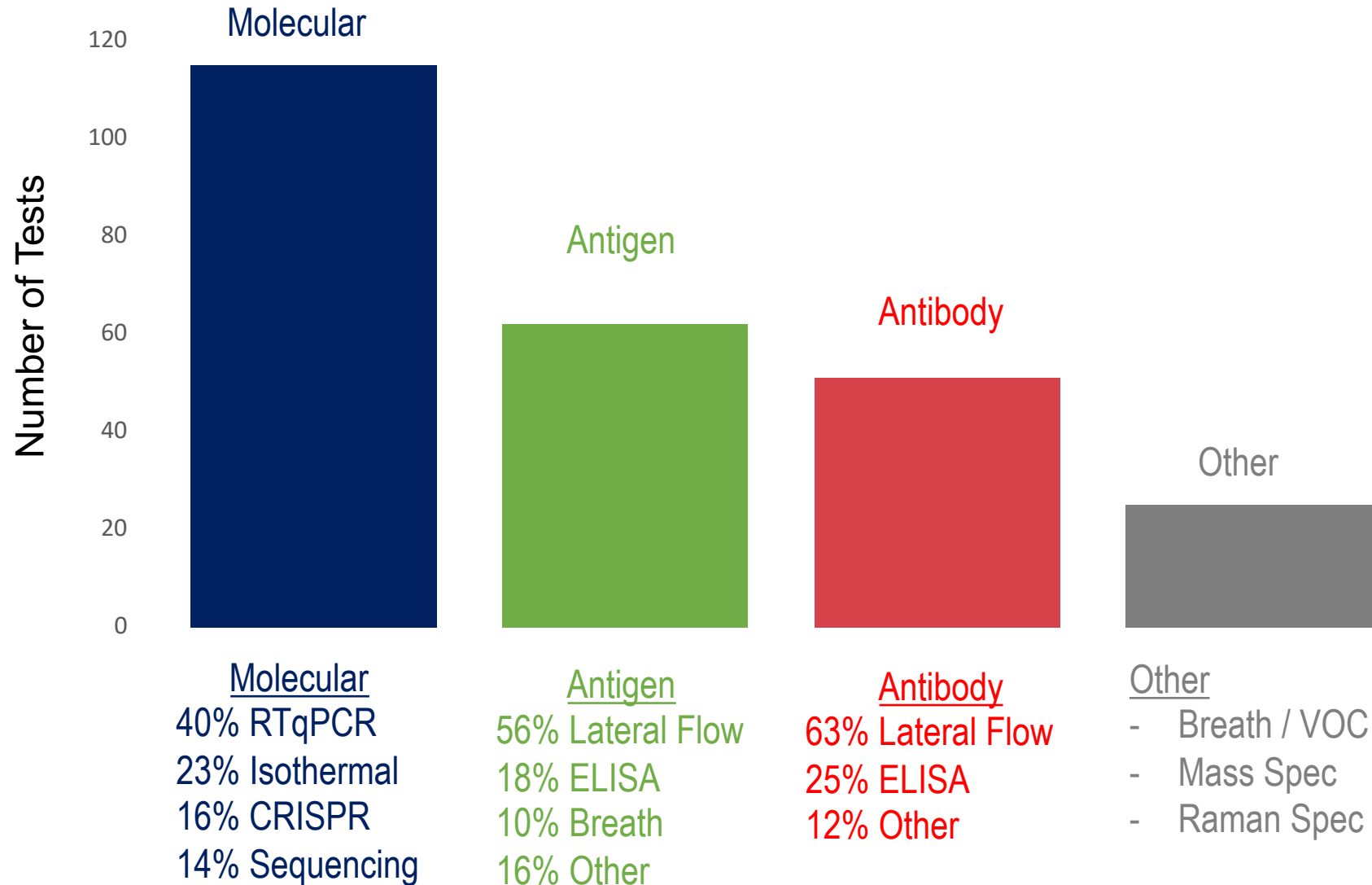
Pandemic Total
through 6/30/21

Research Use Only Tests Authorized outside of US & EU



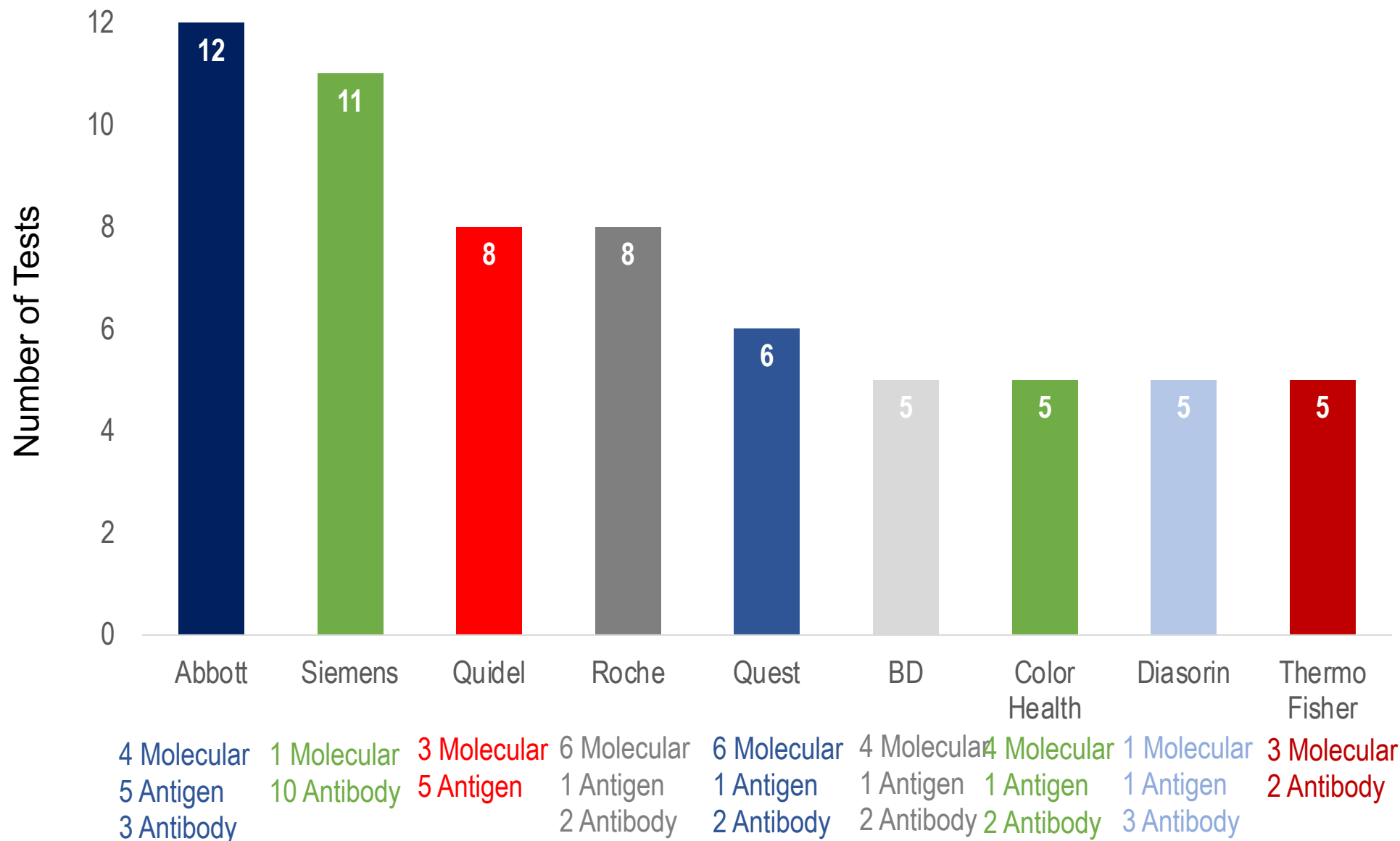
Pandemic Total
through 6/30/21

Tests in Development Worldwide



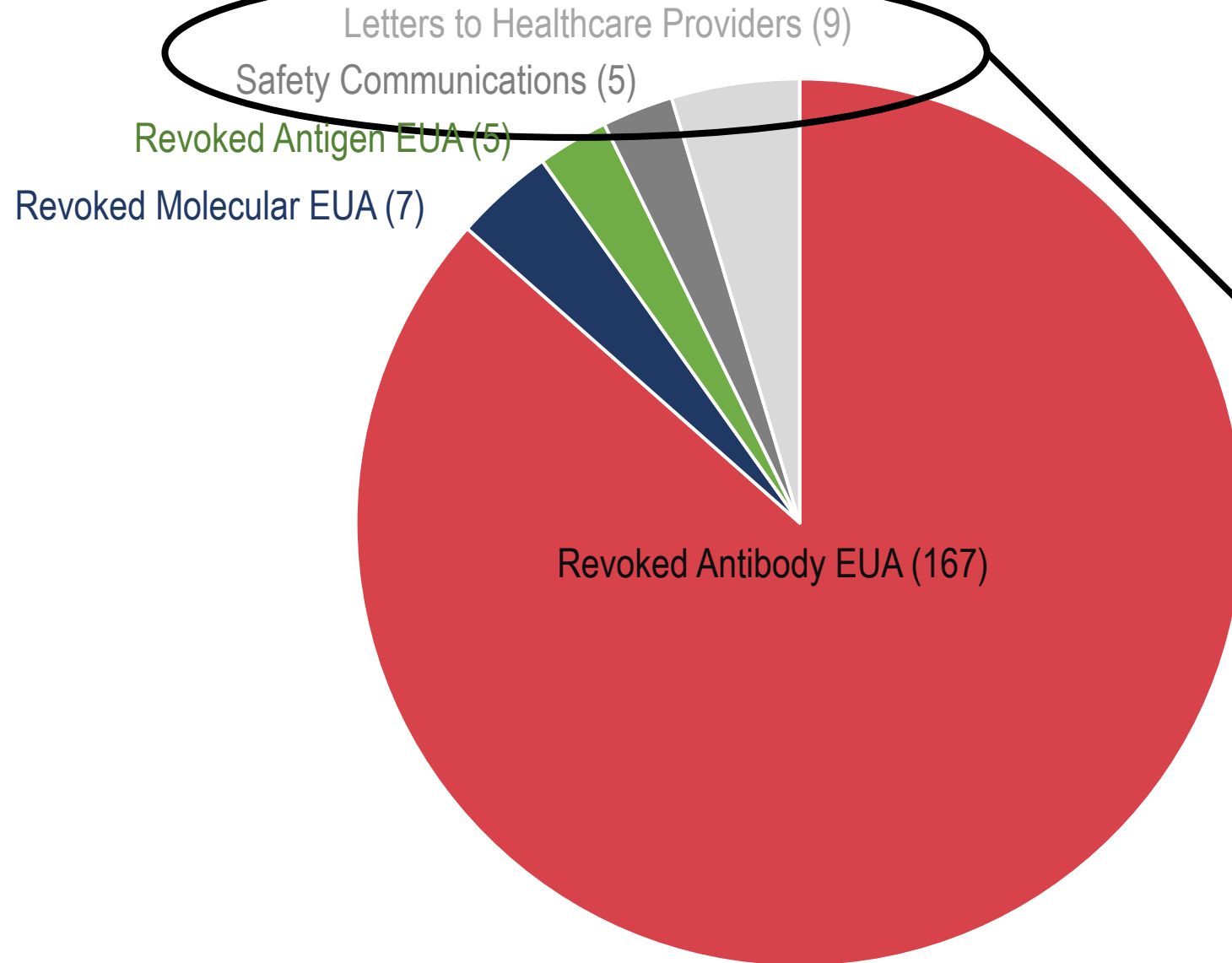
Pandemic Total
through 6/30/21

Companies with the largest number of EUAs



Pandemic Total through 6/30/21

FDA Revoked EUA's and Other Safety Communications



- **Safety Communications:** FDA posts Medical Device Safety Communications to describe FDA's analysis of a current issue and provide specific regulatory approaches and clinical recommendations for patient management.
- **Letters to Healthcare Providers:** FDA posts the letters it sends to health care providers about safety concerns with medical devices used in health care facilities.

Pandemic Total through 6/30/21

Other FDA Safety Communications by Subject

Letters to Health Care Providers

- BD Max
- ThermoFisher
- Roche

Letters to Health Care Providers

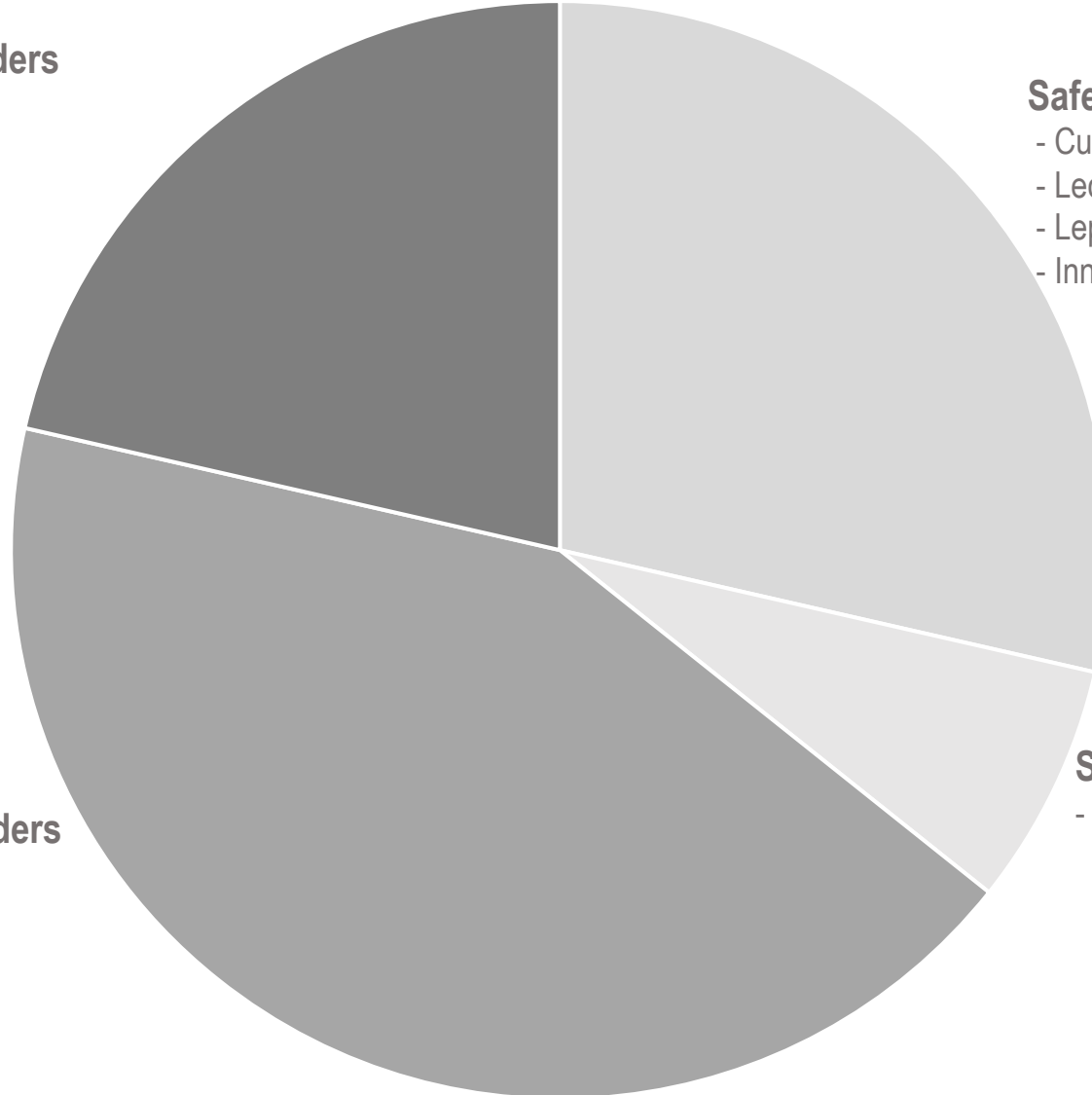
- Antibody Testing (2)
- Transport Media
- Self Testing / Nasal Swabs
- Rapid Antigen Tests
- Variants

Safety Communications

- Curative
- Leccurate
- Lepu Medical
- Innova

Safety Communications

- Antibody Testing



Pandemic Total
through 6/30/21

EUA's for Management of COVID-19 Patients

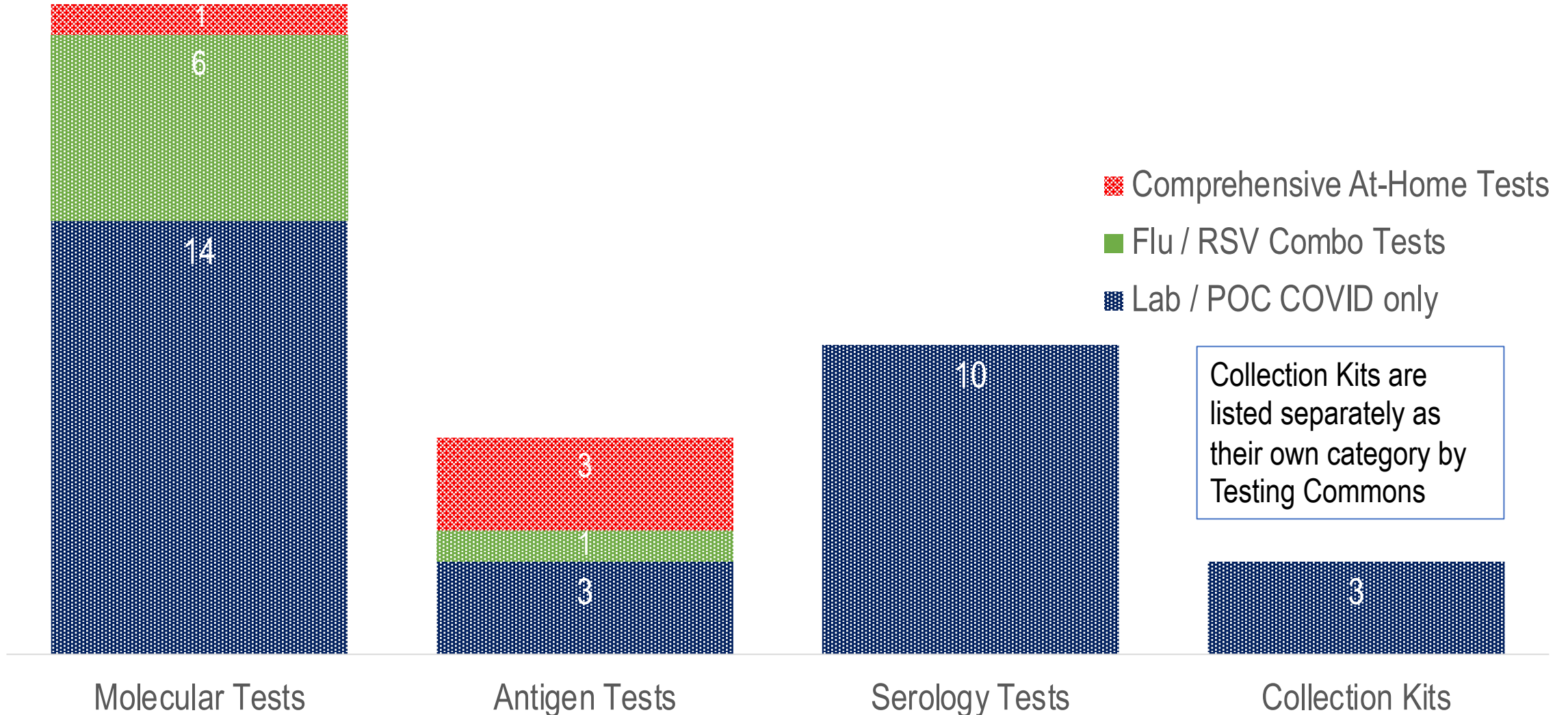


IVDs for Management of COVID-19 Patients (3)

- Roche Diagnostics Elecsys IL-6 (June 2020)
- Beckman Coulter, Inc. Access IL-6 (October 2020)
- Siemens Healthcare Diagnostics Inc. ADVIA Centaur IL6 Assay (December 2020)

New EUAs by Technology Q1 2021 (n=41)

Total Q1 2021 New EUA's



New EUAs by Technology Q2 2021 (n=43)

Total Q2 2021 New EUA's

